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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,711	08/05/2003	William F. McKay	4002-3365	8938
52196	7590	09/23/2005	EXAMINER	
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			SNOW, BRUCE EDWARD	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,711

Applicant(s)

MCKAY, WILLIAM F.

Examiner

Bruce E. Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 30 and 32-65 is/are pending in the application.
- 4a) Of the above claim(s) 3-8, 14, 34, 35, 39-41, 47-54, 64 and 65 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9-11, 13, 15, 30, 32, 33, 36-38, 42, 44, 45 and 55-63 is/are rejected.
- 7) ☒ Claim(s) 12 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/4/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 7/19/05 have been fully considered. Regarding the rejection in view of Grosse et al, referring to at least figures 4 and 14 thereof, the implants are interpreted as having a truncated surface as compared with the embodiment shown in figure 15, and is fully capable of being nested.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: dumbbell.

Information Disclosure Statement

The information disclosure statement filed April 4, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. No copies were provided.

Allowable Subject Matter

Claim 43 is allowed.

Claims 12 and 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 10, 15-16 and 57-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Grosse et al (WO 97/23174).

Grosse et al teaches a spinal implant system comprising at least first and second load bearing members (see figures 4-5), said loading bearing members comprising opposite end pieces 5a, 5b having opposite surfaces configured to contact and support

adjacent vertebrae; a longitudinally "central" element 6 connecting the end portions; and an osteogenic material 2 or 10 having a consistency so as to be retainable "about" (approximately) said central element. Note that the central element is less in height than elements 5 forming a pocket between the central element and adjacent vertebrae.

Referring to figure 14, the end pieces are interpreted as being truncated having a flat side in comparison to the configured shown in figure 15. The flat side allows the implant to be more closely nested.

Regarding claim 18, the claim only claims "configured to be nested".

Claim 19, the implants as shown in figures 4-5 are interpreted as being "nested" together in the same vertebrae space.

Claims 1-2, 9-11, 13, 15, 30, 32-33, 36-38, 42, 57-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Brosnahan, III (5,645,598).

Referring to at least figure 13-14, Brosnahan, III teaches a spinal implant system comprising at least first and second load bearing members; see column 5, lines 46 et seq. teaching the nesting of two, said loading bearing members comprising opposite end pieces having opposite surfaces configured to contact and support adjacent vertebrae; a longitudinally "central" elements connecting the end portions; and an osteogenic material 40 including BMP having a consistency so as to be retainable "about" (approximately) said central elements defining the opposite end pieces. Note figure 14 showing a concave truncated surface.

Regarding claim 11 requiring a carrier, see at least column 4, lines 8 et seq.

Regarding at least claim 20, "around" does not mean bone growth material completely surrounds the central body (central element of claim 1).

Regarding claim 31, "the tool", see tool receiving element 32, the tool is inherent.

Regarding claim 42, nesting the implant does not mean the implants have to be in direct contact with each other, obviously forming a pocket between the two.

Additionally, if the implant were positioned in direct contact, a pocket 40 is formed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 9-11, 13, 15, 30, 32, 33, 36-38, 42, 44, 45, 55-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich (DE 19630256) in view of Michelson (6,123,705).

Ulrich teaches a first cylindrical fusion device being dumbbell shaped including a opposing end pieces 17, 18 and a central element 19 connecting said opposing end pieces. However, Ulrich fails to teach nesting a second dumbbell fusion device with the first. Michelson also teaches cylindrical fusion devices which are nested together by utilizing a cutout region; see at least figure 25, elements 406, 408; and figure 43, concave cutout region 902. It would have been obvious to one having ordinary skill in the art to have utilized the teachings of Michelson of nesting two fusion device together

with the fusion devices of Ulrich because *"two cylindrical implant considered to be the preferred number as it is a much more stable construct and has more surface area than a single implant placed centrally (column 2, lines 18-20)"* and to include a cutout region *"when it is desirable to insert two implants side-by-side into cylindrically prepared channels, and where the height of the disc space between two adjacent vertebra is so great relative to the transverse width of the spine"* such that two implant fit within the transverse width (column 3, lines 40 et seq.).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

A handwritten signature in black ink, appearing to be 'BS' followed by a long horizontal stroke.

BRUCE SNOW
PRIMARY EXAMINER